



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/DK99/00387  (22) International Filing Date: 05 July 1999 (05.07.1999)  (30) Priority Data: PA 1998 00910      08 July 1998 (08.07.1998) DK PA 1998 01501      17 November 1998 (17.11.1998) DK  (60) Parent Application or Grant NOVO NORDISK A/S [/]; O. BUCH-RASMUSSEN, Thomas [/]; O. MUNK, Benny [/]; O. POULSEN, Jens-Ulrik [/]; O. LJUNGREEN, Henrik [/]; O. JENSEN, Peter, Moller [/]; O. JENSEN, Jens, Moller [/]; O. HOIBERG APS; O.	<b>Published</b>	
(54) Title: <b>A MEDICATION DELIVERY DEVICE AND A CARTRIDGE ASSEMBLY FOR USE IN THE SAME</b> (54) Titre: <b>DISPOSITIF D'APPORT D'UN MEDICAMENT ET ENSEMBLE CARTOUCHE A UTILISER AVEC CELUI-CI</b>		
(57) Abstract		
<p>The present invention relates to a medication delivery device comprising a cartridge assembly, a dosing assembly and optionally a needle assembly. The cartridge assembly comprises a cartridge having a stopper adapted to receive a plunger means. Furthermore, the cartridge assembly has one end sealed with a pierceable sealing, said end comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly. The dosing assembly comprises a plunger means and has coupling means for engaging the cartridge assembly. The cartridge assembly and the dosing assembly are coupled together for delivering selected doses of medication. The device further comprises means for securing that the plunger means abuts on the stopper during use of the device, in particular when the dosing assembly is releasably coupled to the cartridge assembly. The securing means is preferably a means for preventing the cartridge assembly from being inadvertently released from the dosing assembly. The cartridge is preferably moulded from a plastic material, such as a transparent material, and may be housed in a cartridge housing protection of the cartridge. The medication delivery device is especially suitable for delivering insulin, growth hormone or the like medicines.</p>		
(57) Abrégé		
<p>L'invention concerne un dispositif d'apport d'un médicament, comprenant un ensemble cartouche, un ensemble doseur, ainsi qu'éventuellement un ensemble aiguille. L'ensemble cartouche comprend une cartouche doté d'un bouchon conçu pour recevoir un piston, et il présente en outre une première extrémité, scellée à l'aide d'un scellement pouvant être percé, et dotée de moyens de couplage avec un ensemble aiguille, son autre extrémité comportant des moyens de couplage avec l'ensemble doseur. Cet ensemble doseur comprend un piston ainsi que des moyens de couplage avec l'ensemble cartouche. L'ensemble cartouche et l'ensemble doseur sont couplés pour distribuer des doses choisies d'un médicament. Le dispositif de l'invention comprend encore des moyens faisant en sorte que le piston bute contre le bouchon lors de l'utilisation du dispositif, notamment lorsque l'ensemble doseur est couplé de manière amovible avec l'ensemble cartouche, ces moyens étant, de préférence, destinés à empêcher l'ensemble cartouche d'être séparé, fortuitement, de l'ensemble doseur. La cartouche est moulée dans une matière plastique, telle qu'une matière transparente, et elle peut être logée dans un boîtier destiné à sa protection. Ce dispositif d'apport de médicament est notamment conçu pour l'apport de médicaments du type insuline, hormone de croissance et analogue.</p>		

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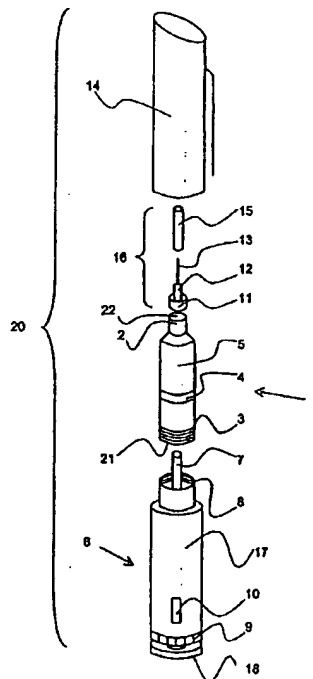
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(54) Title: A MEDICATION DELIVERY DEVICE AND A CARTRIDGE ASSEMBLY FOR USE IN THE SAME

(57) Abstract

The present invention relates to a medication delivery device comprising a cartridge assembly, a dosing assembly and optionally a needle assembly. The cartridge assembly comprises a cartridge having a stopper adapted to receive a plunger means. Furthermore, the cartridge assembly has one end sealed with a pierceable sealing, said end comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly. The dosing assembly comprises a plunger means and has coupling means for engaging the cartridge assembly. The cartridge assembly and the dosing assembly are coupled together for delivering selected doses of medication. The device further comprises means for securing that the plunger means abuts on the stopper during use of the device, in particular when the dosing assembly is releasably coupled to the cartridge assembly. The securing means is preferably a means for preventing the cartridge assembly from being inadvertently released from the dosing assembly. The cartridge is preferably moulded from a plastic material, such as a transparent material, and may be housed in a cartridge housing protection of the cartridge. The medication delivery device is especially suitable for delivering insulin, growth hormone or the like medicines.



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**Description**

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## 5 A MEDICATION DELIVERY DEVICE AND A CARTRIDGE ASSEMBLY FOR USE IN THE SAME

10 The present invention relates to a medication delivery device having a cartridge assembly and a dosing assembly coupled together for delivering selected doses of medication.

5 **Background**

15 Some medication, such as insulin is self-administered. The typical diabetes patient will require injections of insulin several times during the day. The required insulin dose will vary from patient to patient, and will for each patient often also vary during 20 the day. Each patient will often establish a regimen for the insulin administration adjusted to his or her insulin need as well as lifestyle. Medication delivery pens have been developed to facilitate the self-administration of medication, such as insulin.

15 One prior art medication delivery pen includes a pen body assembly comprising a medication cartridge and a plunger device. A needle assembly may be connected to 25 the pen body assembly. The medication is delivered by moving or pressing a plunger in the direction of the needle assembly thereby delivering the medication. When the medication in the cartridge is exhausted the pen body assembly is discarded. Depending on the medication needs for each individual the medication in 30 the cartridge will last for several days. During this period the needle assembly will often have to be displaced by a new assembly or new needle due to increasing bluntness of the needle making injections painful for the patient.

25 Due to the environmental and economical reasons medication delivery pens were developed, for which pens only a part of the pen was discarded after medication exhaustion, such as the cartridge only.

30 An example of prior art pens is disclosed in EP 0 688 571 wherein a medication delivery pen has a reusable pen body assembly and a disposable cartridge assembly that are threadably engageable with one another. The disposable cartridge assembly includes a plunger and can releasably receive a needle cannula assembly 45 through a threaded coupling. A driving means in the pen body assembly engages the plunger after engagement of the pen body assembly and the cartridge assembly, whereby the pen is ready for dosing the medicine within the cartridge. The cartridge 50

holder assembly can be disassembled from the pen body assembly after the medication therein has been exhausted, discarded and replaced.

However, a drawback of the above-mentioned pen is that the driving means of the pen body may be disengaged from the plunger of the cartridge during normal use resulting in inaccurate dosing of the medicine.

For the device disclosed in EP 0 688 571, the needle assembly will often have to be replaced independently of replacement of the cartridge. When releasing the needle assembly from the cartridge assembly the cartridge assembly may inadvertently be released or partly released from the pen body assembly. Thereby the driving means of the pen body may be disengaged from the plunger of the cartridge. In particular if the pen body assembly is only partly released from the cartridge assembly the user will most probably not be aware of the disengagement but will receive only a portion or even nothing of the medicine.

Even pens with differently pitched threaded couplings and/or threaded couplings having different diameters whereby the force exerted to fasten and/or release one coupling is greater than the force necessary for the other coupling present this problem. It is easy to imagine that a small obstruction (a sandskorn, for example) to the smoothest going coupling will necessitate a greater force to fasten/release that coupling which force tends towards the force necessary for the other coupling.

Accordingly, it is an object of the present invention to provide a medication delivery device with which the inadvertent disengagement of the driving means and plunger means from the plunger or stopper in the cartridge is avoided.

#### **Summary of the invention**

According to a first aspect of the invention a medication delivery device is provided which comprises

a cartridge assembly, having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for releasably mounting a needle

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assembly, and comprising a cartridge having a stopper adapted to receive plunger means,

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a dosing assembly comprising plunger means,

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and optionally a needle assembly,

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wherein the cartridge assembly and the dosing assembly are coupled together, and the device further comprises means for securing that the plunger means abuts on the stopper during use of the device.

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In a preferred embodiment the dosing assembly is reusable and the cartridge assembly is disposable, and accordingly, a second aspect of the present invention is a medication delivery device wherein the dosing assembly is releasably coupled to the cartridge assembly.

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By the term "use of the device" is meant the normal use, including metering and delivering the medication, removing a cap from the cartridge assembly and/or needle as well as attaching and releasing the needle assembly. It is understood that the plunger means must disengage the stopper when the cartridge assembly is deliberately released from the dosing assembly because the medication in the cartridge has been exhausted and the cartridge assembly is to be discarded. In this situation the plunger means is to be retracted to the dosing assembly before assembling the device with a new cartridge assembly.

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Securing the abutment of the plunger means on the stopper during use of the medication delivery device, in particular when the needle assembly is coupled to and/or decoupled from the cartridge assembly, may be carried out by a variety of means. In a preferred embodiment the abutment is secured by preventing the cartridge assembly from being inadvertently released from the dosing assembly.

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Furthermore, it is a preferred aspect of the invention to provide a medication delivery device, which device is arranged for securing that the plunger means abuts on the stopper during coupling and/or decoupling of the needle assembly.

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In one embodiment of the invention the dosing assembly is coupled to the cartridge assembly at the end of the cartridge assembly opposite the means for mounting the needle assembly, and the plunger means is a rod element adapted to exert an axial movement of the stopper towards the sealed end of the cartridge.

Accordingly, it is an aspect of the present invention to provide a medication delivery device, wherein the means for coupling the dosing assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly does not cause an axial movement of the cartridge assembly with respect to the dosing assembly. In this way it is assured that the rod element does not disengage the stopper in the cartridge when the user attaches the needle assembly or removes it after use. Thereby the user can be confident of the accuracy of the dosage selected.

The means for coupling the dosing assembly and the cartridge assembly together may be any suitable coupling, preferably a releasable coupling. Examples of the coupling are snap locks, such as snap locks with guidewire and sideways snap locks, snap locks released through threads, bajonet locks, luer locks, hinged locks, threaded locks and any suitable combinations thereof.

In particular, when the cartridge assembly is released from the dosing assembly through a movement including an axial movement, such as through a threaded coupling, it is preferred that the means for releasably coupling the needle assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly cannot cause an axial movement of the cartridge assembly with respect to the dosing assembly. Thus, in that respect examples of the preferred couplings between the needle assembly and the cartridge assembly include releasable snap locks. Another preferred embodiment includes a safety on the coupling between the dosing assembly and the cartridge assembly, such as hinge on the coupling or a threaded coupling releasable only after exerting an axial pressure on the coupling.

According to the invention preferred combinations of couplings between the dosing assembly and the cartridge assembly and between the needle assembly and the cartridge assembly, respectively, are a threaded coupling combined with a snap



coupling, a bajonet lock or a luer lock combined with a snap lock, or a snap lock combined with a snap lock, or any other combination for which the couplings are independently working.

Another aspect of the present invention is a cartridge assembly for use in the medication delivery device according to the invention. The cartridge assembly comprises a cartridge for the medication to be delivered. The cartridge assembly has one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for releasable mounting a needle assembly, and another end comprising coupling means adapted to engage a dosing assembly. Furthermore, the cartridge comprises a stopper.

The cartridge assembly may further comprise a housing for protecting at least a part of the cartridge assembly.

In a preferred embodiment at least one of the coupling means of the cartridge assembly is unitarily moulded with the cartridge, and in a more preferred embodiment all the coupling means are unitarily moulded with the cartridge. In the latter case the cartridge assembly may be comprised of just one part, i.e. the cartridge including the coupling means.

In another embodiment the invention relates to a medication delivery device for transferring medication from the cartridge into a syringe with a needle. In this embodiment the coupling means for engaging the needle assembly may be replaced by coupling means for engaging the syringe, or coupling means for both may be provided. The coupling means may be a syringe holder, for example a cylinder coupled to the cartridge comprising a central bore for receiving the syringe. The syringe is coupled to the cartridge having the needle piercing the sealing. By activation of the dosing means the metered amount of medication is driven into the syringe. The syringe is then ready for injection after being removed from the cartridge.

#### Drawings

Fig. 1 is an exploded perspective view of the medication delivery device.

Fig. 2 is a cross-sectional view showing part of the medication delivery device, 2a immediately after assembling before the first injection, and 2b after some time of use.

Fig. 3 is a cross-sectional view showing the cartridge before assembling of the medication delivery device.

#### Detailed description of the invention

A medication delivery device in accordance with the present invention is identified generally by the numeral 20 in Fig. 1 and 2. Medication delivery device 20 includes a dosing assembly 6, and cartridge assembly 1, a needle assembly 16 and a cap 14.

The dosing assembly 6 is illustrated in Fig. 1 and 2. It is understood, however, that the dosing assembly 6 according to the invention may be any suitable dosing unit including plunger means, and accordingly, that variations from the depicted embodiment may be provided, and are considered to be within the scope of this invention. In the depicted embodiment the dosing assembly 6 includes a cylindrical housing surrounding the plunger means 17 of the dosing unit and having opposed proximal and distal ends.

In one aspect of the invention the plunger means comprises a rod element 7 which is adapted to engage the stopper 4 of the cartridge assembly 1. The rod element 7 advances axially into the cartridge 5 during injections. The dosing assembly may have any suitable driving means for advancing the rod element 7.

The dosing unit 6 preferably also comprises scale means 10 indicating the dosing quantity selected by activating the dose setting means 9 for defining specified selected doses of medication to be delivered. The selected dose may be delivered by actuating the actuator button 18. The actuator button is part of the driving means of the dosing assembly exerting its force on the rod element 7.

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The dosing assembly further comprises coupling means 8 adapted for engagement with the cartridge assembly. The coupling means 8 may be internal or external couplings. In a preferred embodiment the coupling 8 is an internal coupling.

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5 The cartridge assembly 1 is illustrated in Fig. 1 and 2, and in greater detail in Fig. 3. In Fig. 1 cartridge assembly 1 includes a moulded cartridge 5 extending from proximal end 21 to distal end 22.

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10 At the distal end 22 of the cartridge assembly 1 is provided coupling means 2 for releasably mounting a needle assembly 11. At the proximal end 21 of the cartridge assembly 1 is provided coupling means 3 for mounting a dosing assembly 6. The coupling means are as described above.

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15 Cartridge 5 also comprises a stopper 4 in sliding fluid tight engagement within said cartridge 5. The stopper 4 is adapted to receive the plunger means, such as a rod element 7 of the dosing assembly 6.

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30 The cartridge assembly 1 may further comprise a housing for protecting some or all of the cartridge 5. When the cartridge assembly 1 includes a housing, one or both of the couplings 2, 3 of the cartridge may be moulded unitarily with the housing.

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35 In a preferred embodiment at least one of the couplings 2, 3 is moulded unitarily with the cartridge 5, minimising the total number of parts of the device and thereby the production costs. Also, a very precise coupling is obtained, since no further steps are to be taken to attach the coupling means to the cartridge.

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Instead of the protective housing the cartridge 5 may have integrally moulded reinforcements of the cartridge wall.

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30 The depicted cartridge 5 is cylindrical having couplings 2, 3 at opposed ends. However, the cartridge may obtain any suitable form and the cross-section may be circular or non-circular, such as substantially triangular or oval.

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35 In Fig. 1 and Fig. 2 the couplings 2, 3 are opposing each other having the same axis. However, the axis of coupling 2 may be arranged to be separate from coupling

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3, that is in any angle with respect to the axis of coupling 3. Thus, the axis of coupling 2 may be perpendicular to the axis of coupling 3, or they may be parallel but not overlapping.

5 A suitable choice of material allows the cartridge to be at least partly transparent, whereby the user can see whether any content, such as a liquid is left in the cartridge.

Referring to Fig. 3 the coupling means of the cartridge are shown in greater detail. 10 The coupling means 3 is an external thread, whereas the coupling means 2 is a recess for a snap lock of the needle assembly. Both coupling means are moulded unitarily with the cartridge.

The device according to the invention may include a protective cap 14 that is removably mounted over the cartridge assembly 1 and/or the needle 11 and which is removed before injection of the medication in the cartridge 5. The cap further ensures that the content of the cartridge is protected against sunlight.

The various parts of the medication delivery device are advantageously made of plastics, e.g. by injection moulding.

The medication delivery device 20 may further comprise any appropriate needle assembly 11, such as a double ended needle 13 having opposed proximal and distal points and a lumen extending axially therebetween.

25 A mounting hub 12 is engaged on the needle 13 and is removably connected to the coupling means 2 at the needle end of the cartridge assembly. The relative location of the mounting hub 12 ensures that the proximal point of the needle 13 will pierce the sealing when the mounting hub 12 is engaged with the coupling means 2 on the cartridge assembly 1.

30 The needle assembly 11 may further comprise a removable shield or cap 15 for protecting against accidental needle sticks.

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The device according to the invention is suitable for delivering pre-set dosages of insulin, it is however understood that the device is suitable for the injection of pre-set dosages of other liquids.

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5 In use the user will set the dose by means of the dose setting means 9. Before activating the actuator button 18 the cap 14 must be removed from the cartridge assembly 1 whereby the device 20 is prepared for an injection. The injection is effected by activating the actuator button 18, which again will effect the stopper 4 to be moved towards the needle at the sealed end 22 of the cartridge 5, thereby delivering the desired pre-set dosage. A subsequent dosage of medication will be set in exactly the same manner as described above. However, for such a subsequent dosage, the rod element 7 and the stopper 4 will be in a partly advanced position as starting point. Dose setting and injections can be carried out until all of the medication has been used.

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## Claims

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Claims:

1. A medication delivery device comprising

5 a cartridge assembly, having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for releasably mounting a needle assembly, and comprising a cartridge having a stopper adapted to receive plunger means,

10 a dosing assembly comprising plunger means,

and optionally a needle assembly,

15 wherein the cartridge assembly and the dosing assembly are coupled together, and the device further comprises means for securing that the plunger means abuts on the stopper during use of the device.

2. A medication delivery device according to claim 1, wherein the dosing assembly is releasably coupled to the cartridge assembly.

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3. A medication delivery device according to any of the preceding claims, wherein the device is arranged for securing that the plunger means abuts on the stopper during coupling and/or decoupling of the needle assembly.

25 4. A medication delivery device according to any of the preceding claims, wherein the plunger means comprises a rod element adapted to exert an axial movement of the stopper towards the sealed end of the cartridge.

30 5. A medication delivery device according to any of the preceding claims, wherein the means for releasably coupling the dosing assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly does not cause an axial movement of the cartridge assembly with respect to the dosing assembly.

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6. A medication delivery device according to any of the preceding claims, wherein the dosing assembly is released from the cartridge assembly through a movement including an axial movement.

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5 7. A medication delivery device according to claim 6, wherein the dosing assembly is released from the cartridge assembly through a threaded coupling.

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8. A medication delivery device according to any of the preceding claims, wherein the dosing assembly comprises scale means.

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9. A medication delivery device according to any of the preceding claims, wherein the dosing assembly comprises dose setting means for defining specified selected doses of medication to be delivered.

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15 10. A medication delivery device according to any of the preceding claims, wherein the cartridge assembly comprises a housing.

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11. A medication delivery device according to any of the preceding claims, wherein the cartridge is unitarily moulded with at least one coupling means.

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12. A medication delivery device according to any of the preceding claims, further comprising a cap for protecting the needle assembly and/or the cartridge assembly.

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25 13. A cartridge assembly for use in the medication delivery device as claimed in any of claims 1-12, having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means adapted to engage a dosing assembly, further comprising a cartridge said cartridge comprising a slidable stopper.

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14. A cartridge assembly according to claim 13, further comprising a housing.

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35 15. A cartridge assembly according to claim 13 or 14, wherein the cartridge is unitarily moulded with at least one coupling means.

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16. A cartridge assembly according to any of claims 13-15, wherein the coupling means adapted to engage the dosing unit is such that coupling and/or decoupling of the needle assembly does not cause an axial movement of the cartridge assembly with respect to the dosing assembly.

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17. A cartridge assembly according to any of claims 13-16, wherein the dosing assembly is released from the cartridge assembly through a movement including an axial movement.

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18. A cartridge assembly according to claim 17, wherein the dosing assembly is released from the cartridge assembly through a threaded coupling.

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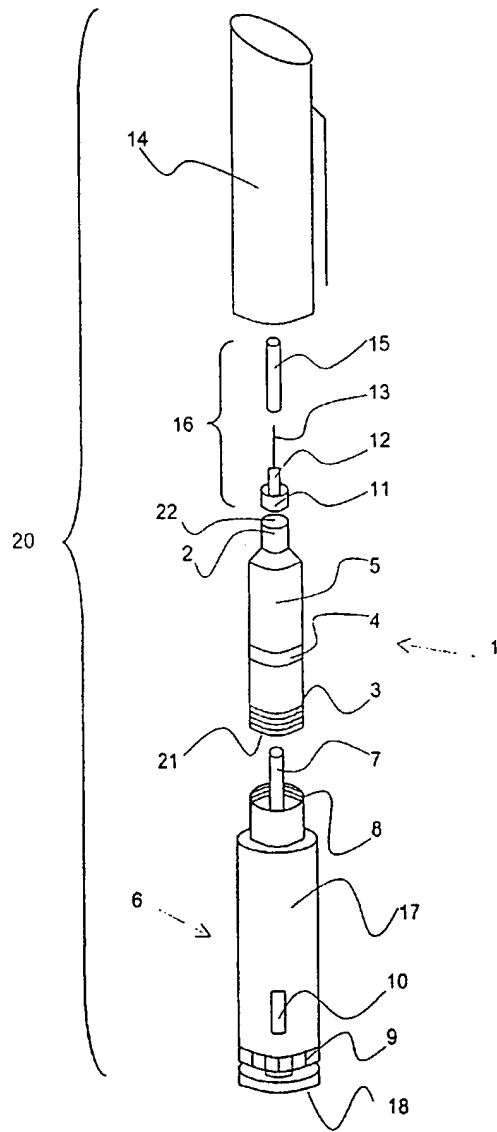


Fig. 1

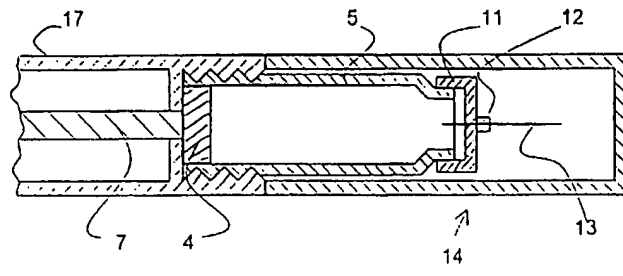


Fig. 2 a

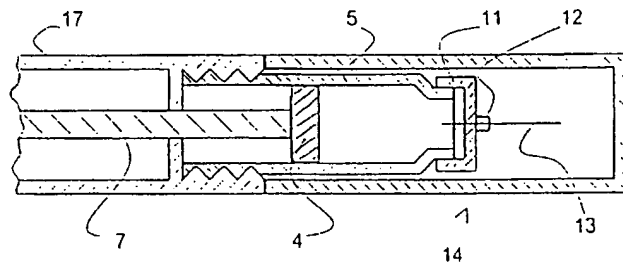


Fig. 2 b

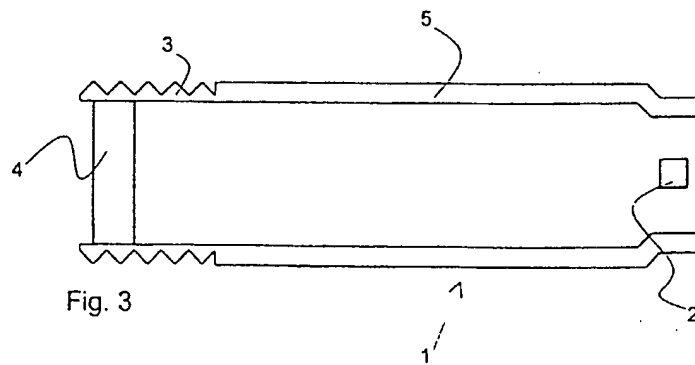


Fig. 3

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/DK 99/00387

<b>A. CLASSIFICATION OF SUBJECT MATTER</b>		
IPC7: A61M 5/24, A61M 5/315 According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b>		
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SE,DK,FI,NO classes as above		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
EPODOC, WPI		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0688571 A1 (BECTON DICKINSON AND COMPANY), 27 December 1995 (27.12.95), column 5, line 40 - column 11, line 30, figures 7-11 --	1,2,4-10, 12-14,16-18
X	US 5688251 A (L.H. CHANOCH), 18 November 1997 (18.11.97), column 3, line 51 - column 8, line 20, figures 12-14 -----	1,2,4-8,10
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Information on patent family members

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